

## REMARKS

As filed, claims 1-9 were pending in the case. In the Response dated March 6, 2003, claim 3 was cancelled and claims 10-13 were added. Additionally, independent claim 1 was amended. In the Office Action dated June 3, 2003, claims 1, 2, and 4-13 were withdrawn from consideration because the amended claim 1 and new claim 10 were found to be directed toward an invention independent or distinct from the invention originally claimed. The Response dated March 6, 2003 was found to be non-responsive as a result.

To provide claims more similar to those filed, this response cancels claims 1, 2, and 4-13 and adds new claims 14-28. The new claims do not add new matter as support is provided in the originally filed claims 1-9 and in Figure 60 with its supporting text at pages 75-79 of the specification). Further, because the new claims include similar structure and limitations as originally filed claim 1 and with additions that would have been expected during prosecution of that claim, it is believed that the original search was drawn to the subject matter of the new claims.

Claims 14-28 remain in the case for consideration by the Examiner.

### **Objections to the Drawings**

In the Office Action of October 1, 2002, the drawings were objected to as now showing every feature of the claimed invention. The new claims have been drafted to avoid this objection, i.e., "a spring means" is not an element, and it is believed this objection has been addressed.

### **Rejections Under 35 U.S.C. § 112**

Also in the October 1, 2002 Office Action, Claim 1 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite because a "piston" limitation did not have antecedent basis. Claim 1 has been cancelled, and it is believed that the newly-presented claims include proper antecedent basis for the claim limitations.

### **Rejections Under 35 U.S.C. § 103**

In the October 1, 2002 Office Action, Claims 1-9 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,788,662 ("Antanavich") in view of U.S. Patent No. 5,582,596 ("Fukunaga"). Claims 1-9 have been cancelled, and it is believed that

new claims 14-28 overcome this prior rejection. The following remarks describe features of the claimed invention which Applicants believe are not shown or suggested by the combination of Antanavich and Fukunaga.

Claim 14 is directed to a platelet gel dispenser that includes first and second vessels each with an opening that provides the inlet and outlet to the particular vessel. A “restoration agent and an activation agent” are positioned within the chamber of the first vessel prior to the receipt of a liquid such as processed blood. The dispenser further includes means for drawing a liquid into and forcing a liquid out of the chambers of the first and second vessels. The cited art does not show or suggest a device with two vessels and that has both a restoration agent and an activation element within a single chamber of the first vessel. Hence, claim 14 is believed allowable over the cited art.

More particularly, the Office Action cites Antanavich at Figures 7 and 8, col. 15, lines 1-34 and col. 21, lines 1-53 for teaching a first and second hollow body having an opening at one end, a restoration agent positioned within the first body and an activation agent. However, Antanavich in Figures 7 and 8 illustrates a single body or vessel with two chambers, i.e., an inner cylindrical chamber 31 and an outer or annular chamber 32. Antanavich fails to show or suggest the use of two vessels as required in claim 1.

Instead, it teaches using a single vessel for storing a previously processed sample of blood is stored in the cylindrical chamber 31 (“a separately-prepared solution containing amounts of thrombin and calcium” as discussed at col. 15, lines 1-3) and concentrated platelet rich-plasma is stored in the outer chamber 32. These two fluids are then mixed in the coaxial needle 33 when the plunger is depressed concurrently forcing the fluids out of both chambers of the single vessel or body. In contrast, claim 14 calls for a restoration agent to be placed in the chamber of the first vessel “prior to the receipt of the liquid.” Antanavich instead teaches mixing the calcium or restoration agent into the liquid and then placing the restored liquid into the chamber 31 (which may be clotting). Similarly, Antanavich teaches activating the liquid in a separate chamber to express thrombin and then storing the thrombin in the cylindrical chamber 31. Claim 14, instead, calls for placing the activation agent in the chamber of the first vessel, which allows the thrombin to be expressed within the chamber of the first vessel.

This is a very different arrangement than called for in Antanavich, and is not shown or suggested. The Office Action states that Antanavich does not show that an activation agent is

in the first vessel but this is a mere design choice because Applicants did not state that there was a surprising result. However, Antanavich teaches activating, at least in large part, prior to insertion in the vessel. Further, Antanavich teaches at col. 21, line 51 that sealant is achieved in “15 minutes” whereas Applicants dispenser is said at page 76, lines 9 and 10 to “obtain thrombin and then produce the platelet gel compositions in an expedited manner, that is, in less than three minutes.” The dispenser of claim 14 facilitates additional processing (expressing of thrombin) than Antanavich yet has been found to be at least 12 minutes faster, and this amount of time can be critical in an operating room environment. Applicants do not agree that the placement of the activation agent within the chamber of the first vessel is an obvious choice with Antanavich and others teaching the preferability of processing separately to obtain thrombin (i.e., teaching away). Independent claim 14 is believed allowable over Antanavich in view of Fukunaga, which is only cited for teaching a spring means (which is no longer a feature of claim 1) and a filter. Because Fukunaga does not overcome the deficiencies of Antanavich, claim 14 is not suggested or made obvious by the combination of these references.

Claims 15-21 depend from Claim 14 and are believed allowable for at least the reasons for allowing Claim 14. Additionally, Claim 15 calls for a filter that is positioned outside the first vessel chamber with a pore size selected to filter clot debris. Antanavich in Figures 7 and 8 does not show a filter let alone one that would be sized for filtering clot debris (as Antanavich teaches obtaining the thrombin prior to insertion in the chamber 31). Fukunaga is cited at Figures 3, 10, and 12 and col. 6, lines 56-67 in the Office Action for showing a filter. However, the only filter shown is sterilizing filter 29 in Figure 3 which is a small pore filter used “for sterilizing the gas fed from a pressurized gas source” (see, Figure 3 and col. 5, lines 37-38). Hence, these references together fail to suggest the usefulness of a filter in a platelet gel dispenser. Claim 16 calls for separate lines to the two vessels not shown by Antanavich and also calls for valving means for selecting flow to either or both vessels, which is not shown in Antanavich or Fukunaga. Hence, claims 15 and 16 are allowable over the cited art for these additional reasons.

Independent claim 22 is directed to a dispenser similar to claim 15 but calls for a lumen connected to the openings of the first and second vessels and a filter element positioned within the first vessel. As with claim 14, the dispenser differs from that shown in Figures 7 and 8 of Antanavich because it includes two vessels rather than one, which is

further stressed or indicated by the use of a lumen that is separately connected to the two openings (whereas there is only one outlet to the vessel of Antanavich which allows mixing at the outlet). Antanavich further does not teach that a filter element should be placed in the first vessel. As discussed above, Antanavich and Fukunaga fail to teach the use of a liquid filter, and clearly do not teach placing the filter within the first vessel (i.e., the only filter shown is gas filter and is shown outside the syringes in Fukunaga). The filter element further is selected to comprise the activating agent for expressing thrombin. This is not taught by either of the references, with Antanavich teaching thrombin is already expressed when the thrombin and calcium mixture is placed in chamber 31 (in other words, “what motivation would there be to place an activation element within the chamber 31?”). Because this two function element within a vessel is not shown or suggested, claim 22 is believed allowable over the cited references.

Claims 23-28 depend from independent claim 22 and are believed allowable for the reasons for allowing claim 22. Further, claim 23 calls for a restoration agent for restoring clot-forming processes within the first vessel. Antanavich does not teach placing a restoration agent within a gel dispenser but instead teaches separate processing with calcium being introduced prior to insertion within the chamber 31. In practice, the multi-chamber device in Figures 7 and 8 of Antanavich would not be useful for the applications that the device in claim 24 would be, i.e., for receiving platelet rich plasma and obtaining thrombin and then creating the gel. Antanavich and Fukunaga do not teach a filter as called for in claim 27 with large micron size between the outlet of the first chamber and the lumen (with the only filter being the gas filter in Fukunaga). For these additional reasons, claims 23 and 27 are believed allowable over the cited combination of references.

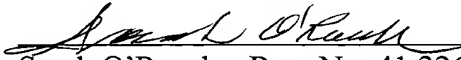
### Conclusions

Based on the above remarks, all pending claims are believed to be allowable over the above-discussed references. Consequently, the case is believed to be in condition for allowance, and this action is respectfully requested.

No fees are believed due with this response, but any fee deficiency associated with this submittal may be charged to Deposit Account No. 50-1123.

Respectfully submitted,

Date July 3, 2003

  
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